DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 17, 2014

Aurora Spine, Incorporated
% Mr. Justin Eggleton
Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street Northwest, 12th Floor
Washington, District of Columbia 20005

Re: K141317
Trade/Device Name: ZIP™ MIS Interspinous Fusion System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: September 17, 2014
Received: September 18, 2014

Dear Mr. Eggleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141317

Device Name
ZIP™ MIS Interspinous Fusion System

Indications for Use *(Describe)*

The Aurora Spine ZIP™ MIS Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. The Aurora Spine ZIP™ MIS Interspinous Fusion System is intended for use with bone graft material and is not intended for stand-alone use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Contact: Justin Eggleton
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Date Prepared: November 17, 2014

Device Trade Name: ZIP™ MIS ULTRA Interspinous Fusion System
ZIP™ MIS Interspinous Fusion System

Manufacturer: Aurora Spine, Inc.
1920 Palomar Point Way
Carlsbad, CA 92008

Common Name: Interspinous Fusion Device

Classification: 21 CFR §888.3050; Spinal interlaminal fixation orthosis

Class: II

Product Code: PEK

Summary of Technological Characteristics:
The purpose of this Special 510(k) is to introduce a line extension (ZIP™ Flared) to the Aurora Spine ZIP™ MIS Interspinous Fusion System that accommodates spinal level between T1 and S1 with greater lordosis. There have been no changes to the intended use of the device or its fundamental scientific technology.

Indications For Use:
The Aurora Spine ZIP™ MIS Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. The Aurora Spine ZIP™ MIS Interspinous Fusion System is intended for use with bone graft material and is not intended for stand-alone use.

Device Description:
The Aurora Spine ZIP™ MIS Interspinous Fusion System is a bilateral locking plate system which attaches to the posterior noncervical spine at the spinous processes. The implants have superior and inferior surfaces and a central chamber for receiving bone graft. The devices are available in a variety of cylinders to accommodate variations in pathology and patient anatomy. The Aurora Spine ZIP™ MIS Interspinous Fusion System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral spine.

Predicate Device:
The modified Aurora Spine ZIP™ MIS Interspinous Fusion System is substantially equivalent to the predicate Aurora Spine ZIP™ MIS Interspinous Fusion System (K140715, K133091) with respect to indications, design, function, performance and materials.

Non-Clinical Testing:
Finite Element Analysis (FEA) testing was provided to demonstrate substantial equivalence of the modified components compared to the predicate ZIP™ MIS system. FEA testing showed the additional geometries of the subject device do not offer a worst-case scenario as compared to the predicate ZIP™ MIS Interspinous Fusion System components.

Conclusion:
The Aurora Spine ZIP™ MIS Interspinous Fusion System has been modified to include modified spinous process fusion plates with different angles and spike orientations to accommodate varying degrees of lordosis. Substantial equivalence has been demonstrates to predicate ZIP™ MIS Interspinous Fusion System 510(k)s.